Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038

U.S. ENVIRONMENTAL PROTECTION AGENCY			AGENCY USE ONLY
EPA	PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES		Date of receipt:
When completed, send this form to:	If sending by Courier: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1201 Constitution Ave NW WASHINGTON, D.C. 20460 Contact Numbers: 202-564-8930/8940	If sending by US Mail: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1200 Pennsylvania Ave NW WASHINGTON, D.C. 20460	Submission Report Number 31AU101012165639379

Total Number of Pages	User Fee Payment ID Number	TS Number
192	TS 700810	700810

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance. For mailing address information see the Help instructions in the e-PMN tool.

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III – LIST OF ATTACHMENTS

For paper submissions, attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

[X]	Environmental fate data	[X]	Other Data
[X]	Health effects data	[X]	Risk Assessments
[X]	Environmental effects data	[ ]	Structure/activity relationships
[X]	Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.)		
[ ]	Test data not in the possession or control of the submitter		

TYPE OF NOTICE (Check Only One)

- [X] **PMN** (Premanufacture Notice)
- [ ] **SNUN** (Significant New Use Notice)
- [ ] **TMEA** (Test Marketing Exemption Application)
- [ ] **LVE** (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
- [ ] **LOREX** (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
- [ ] **LVE** Modification
- [ ] **LOREX** Modification
- [ ] **Mock Submission**
- [ ] Mark (X) if pending Letter of Support

IS THIS A CONSOLIDATED PMN (Y/N)? ____

# of chemicals or polymers (Prenotice Communication # required, enter # on p. 3). ____

- [X] Mark (X) if any information in this notice is claimed as confidential.

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CERTIFICATION -- A printed copy of this signature page, with original signature, must be submitted with CD or paper submission.

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture, import or process for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.
2. All information provided in this notice is complete and truthful as of the date of submission.
3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, Consolidated PMN, or SNUN, check the following **user fee** certification statement that applies:

- [X] The Company named in Part I, Section A has remitted the fee of $2500 specified in 40 CFR 700.45(b), or
- [ ] The Company named in Part I, Section A has remitted the fee of $1000 for an Intermediate PMN (defined @ 40 CFR 700.43) in accordance with 40 CFR 700.45(b), or
- [ ] The Company named in Part I Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45(b).

If you are submitting a **Low Volume Exemption (LVE)** application in accordance with 40 CFR 723.50(c)(1) or a **Low Release and Low Exposure Exemption (LoRex)** application in accordance with 40 CFR 723.50(c)(2), check the following certification statements:

- [ ] The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.
- [ ] The manufacturer is familiar with the terms of this section and will comply with those terms; and
- [ ] The new chemical substance for which the notice is submitted meets all applicable exemption conditions.
- [ ] If this application is for an LVE in accordance with 40 CFR 723.50(c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 USC 1001.

Confidential

Signature and title of Authorized Official (Original Signature Required)		Date		
				☐

Part I -- GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential

1a.	Person Submitting Notice (in U.S.)					Confidential
Name of Authorized Official	(first) Lynn		(last) Tordo			
Position	Regulatory Manager					
Company	Thor Specialities, Inc.					☐
Mailing Address (number & street)	56 Quarry Road					
City	Trumbull	State	CT	Postal Code	06611	
email	ltordo@thorsp.com					

b.	Agent (if Applicable)					Confidential
Name of Authorized Official	(first)		(last)			
Position						
Company						☐
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)		203-365-6530		

c.	Joint Submitter (if applicable)					Confidential
If you are submitting this notice as part of a joint submission, mark (X)					☐	
Name of Authorized Official	(first)		(last)			
Position						
Company						☐
Mailing Address (number & street)						
City		State		Postal Code		
e-mail		Telephone (include area code)				

2.	Technical Contact (in U.S.)					Confidential
Name of Authorized Official	(first) Lynn		(last) Tordo			
Position	Regulatory Manager					
Company	Thor Specialties, Inc.					☐
Mailing Address (number & street)	56 Quarry Road					
City	Trumbull	State	CT	Postal Code	06611	
e-mail	ltordo@thorsp.com	Telephone (include area code)		203-365-6530		

3.	If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number.		Mark (X) if none ☒	Confidential ☐
4.	If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete).		Mark (X) if none ☒	Confidential ☐
5.	If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.		Mark (X) if none ☒	Confidential ☐

6.	Type of Notice – Mark (X)						
1.	Manufacture Only ☐ Binding Option ☐	2.	Import Only ☒ Binding Option ☒	3.	Both ☐		

Part I – GENERAL INFORMATION -- Continued

Section B – CHEMICAL IDENTITY INFORMATION: You must provide a currently correct Chemical Abstracts (CA) name of the substance based on current CA index nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either Item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. ☐

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)	Class 1	Class 2	CBI
a. Class of substance - Mark (X)	☐	X	☐

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, which ever is appropriate based on current CA index nomenclature rules and conventions). X

XXX

CAS Registry Number (if a number already exists for the substance): XXX

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice) ☐ | IES Order Number | | **Method 2** (Other Source) X

Enter Attachment filename for Part I, Section B, 1. c. ☐

d. Molecular formula: XXX X

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance, provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained. ☐

See Attachment 012 (CHEMICAL STRUCTURE_sanitized.pdf)

Enter Attachment filename for Part I, Section B, 1. e.: CHEMICAL STRUCTURE_sanitized.pdf ☐

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For a class 2 substance - (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate).	Confidential

e. (1) List the immediate precursor substance names with their respective CAS Registry Numbers. [X]

XXX

Enter Attachment filename for Part I, Section B, 1. e. (1)		☐

e. (2) Describe the nature of the reaction or process. [X]

XXX

Enter Attachment filename for Part I, Section B, 1. e. (2)		☐

e. (3) Indicate the range of composition and the typical composition (where appropriate). [X]

XXX

Enter Attachment filename for Part I, Section B, 1. e. (3)		☐

Part I -- GENERAL INFORMATION – Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. Polymers (For a definition of polymer, see the Instructions Manual.) | Confidential

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition. ☐

Describe the methods of measurement or the basis for your estimates:

GPC ☐ | **Other** (Specify Below) ☐

Specify Other:

(i) lowest number average molecular weight:	(ii) maximum weight % below 500 molecular weight:	(iii) maximum weight % below 1000 molecular weight:

Enter Attachment filename for Part I, Section B, 2. a. ☐

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential

(1) - Provide the specific chemical name and CAS Registry Number (if a number exists) of each monomer or other reactant used in the manufacture of the polymer.
(2) - Mark (X) this column if entry in column (1) is confidential.
(3) - Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) - Choose "yes" from drop down menu if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) - Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) - Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) - Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant specific chemical name (**1**)	CBI (**2**)	Typical composition (**3**)	Include in identity (**4**)	CBI (**5**)	Max residual (**6**)	CBI (**7**)
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						
CAS Registry Number (**1**)						

Mark (X) this box if the data continues on the next page. ☐

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c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice (check one).				CBI
Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice) ☐	IES Order Number		**Method 2** (other source) ☐	
Enter Attachment filename for Part I, Section B, 2. c.				☐

d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.	☐

CAS Registry Number (if a number already exists for the substance)		

e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.	☐

Enter Attachment filename for Part I, Section B, 2. e.		☐

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. Impurities
   (a) - Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purpose. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
   (b) - Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity (a)	CAS Registry Number (a)	Maximum Percent % (b)	Confi-dential
XXX	XXX	XXX	X
XXX	XXX	XXX	X

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part I, Section B, 3. ☐

4. Synonyms - Enter any chemical synonyms for the new chemical identified in subsection 1 or 2.

XXX

☒

Enter Attachment filename for Part I, Section B, 4. ☐

5. Trade identification - List trade names for the new chemical substance identified in subsection 1 or 2.

AFLAMMIT PCO 700, AFLAMMAN TL 1247

☐

Enter Attachment filename for Part I, Section B, 5. ☐

6. Generic chemical name - If you claim chemical identify as confidential, you must provide a generic name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

Organic-N,P-compound

Enter Attachment filename for Part I, Section B, 6.

7. Byproducts - Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confi-dential
None		

Mark (X) this box if the data continues on the next page. ☐

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

The information on this page refers to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume -- Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume.

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (X)
XXX	XXX	☒	☐

Enter Attachment filename for Part I, Section C, 1.		CBI ☐

2. Use Information -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) --Describe each intended category of use of the new chemical substance by function and application.
(2) --Mark (X) this column if entry column (1) is confidential business information (CBI).
(3) --Indicate your willingness to have the information provided in column (1) binding.
(4) --Estimate the percent of total production for the first three years devoted to each category of use.
(5) --Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) --Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) --Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) --Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.
(9) --Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (**1**) (by function and application i.e. a dispersive dye for finishing polyester fibers)	CBI (**2**)	Binding Option Mark (X) (**3**)	Production % (**4**)	CBI (**5**)	% in Formulation (**6**)	CBI (**7**)	% of substance expected per use (**8**)					CBI (**9**)
							Site-limited	Consumer*	Industrial	Commercial	Binding Option	
XXX	X		XXX	X	XXX	X	XXX	XXX	XXX	XXX		X

* If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

Mark (X) this box if the data continues on the next page. ☐

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instruction Manual for examples of generic use descriptions.

Flame retardant for incorporation into polymer resins (open non-dispersive use)

Enter Attachment filename for Part I, Section C, 2. b.		CBI ☐

3. Hazard Information -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the new substance. List in part III hazard information you include.

Mark (X) this box if you attach hazard information.	☒	Binding Option Mark (X) ☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the "Confidential" box next to any item you claim as confidential

The information on pages 8 and 8a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control. Importers do not have to complete this section for operations outside the U.S.; however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual

1. Operation description
   a. Identity -- Enter the identity of the site at which the operation will occur.

				Confi-dential
Name	Thor Specialties, Inc.			
Site address (number and street)	56 Quarry Road			☐
City	Trumbull	County	New Haven	
State	CT	ZIP code	06611	

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet, and if any of the sites have significantly different production rates or operations, include all the information requested in this section for those sites as attachments. → 1 ☐

Mark (X) this box if the data continues on the next page. ☐

b. Type -- Mark (X) Manufacturing ☐ Processing ☐ Use ☐ ☐ Confi-dential

c. Amount and Duration -- Complete 1 or 2 as appropriate

				Confi-dential
1. Batch	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year	☐
2. Continuous	Maximum kg/day (100% new chemical substance)	Hours/day	Days/year	☐

d. Process description — Mark (X) to indicate your willingness to have your process description binding. → ☐

(1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.).
(2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

☐

Chemical Importer has only warehousing and distribution in the US

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Diagram of the major unit operation steps.	Confidential ☐

Enter Attachment filename for Part II, Section A, 1. d.	☐

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Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

The information on pages 9 and 9a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

2. Occupational Exposure -- You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) -- Describe the activities (i.e. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
(2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) -- Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) -- Indicate your willingness to have the information provided in column (3) or (5) binding.
(5) -- Indicate the physical form(s) of the new chemical substance (e.g., solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
(7) -- Mark (X) this column if entries in columns (3) and (5) are confidential business information (CBI).
(8) -- Estimate the maximum number of workers involved in each activity for all sites combined.
(9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (i.e., bag dumping, filling drums) (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (X) (4)	Physical form(s) & % new substance (5)	Binding Option Mark (X) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum Duration		CBI (12)
									Hrs/Day (10)	Days/Yr (11)	

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part II, Section A on the bottom of page 9a. ☐

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3. Environmental Release and Disposal -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the new substance will be released from that release point.
(5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number	Amount of New Substance Released		CBI	Medium of release e.g. Stack air	Control technology and efficiency (you may wish to optionally attach efficiency data)			CBI
(1)	(2a)	(2b)	(3)	(4)	(5a)	Binding Mark (X)	(5b)	(6)
Mark (X) this box if the data continues on the next page.							☐	

(7) Mark (X) the destination(s) of releases to water.		NPDES#	CBI
☐ POTW--provide name(s)			☐
☐ Navigable waterway- - provide name(s)			☐
☐ Other--Specify			☐
Enter Attachment filename for Part II, Section A.			☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

The information on pages 10 and 10a refer to consolidated chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the new chemical substance*. If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1(a). Operation Description -- To claim information in this section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

(1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify - e.g. 5 gallon pails, 55 gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity.

(2) -- Either in the diagram or in the text field 1(b) below, provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch).

(3) -- Either in the diagram or in the text field 1(b) below, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

(4) -- Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

	Number of Sites	7	Confidential ☐

See Attachment 013 (Warehouse Locations_Sanitized.pdf)

1(b). (Optional) This space is for a text description to clarify the diagram above. Confidential ☐

Resin, Pigment and additives (including 15% PMN substance) enter the process in step A. Based upon a 1000 Ton/year initial import and a 220 day typical operating schedule 4.55 Tons/day is the first year's projected maximum use.

Enter Attachment filename for Part II, Section B on the bottom of page 10a.	Warehouse Locations_Sanitized.pdf ☐

PMN Page 10a

2. Worker Exposure/Environmental Release

(1) -- From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) -- Estimate the number of workers exposed for all sites combined.
(4) -- Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) -- Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.
(7) -- Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) -- From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) -- Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) -- Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) -- Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity	# of Workers Exposed	CBI	Duration of Exposure		CBI	Protective Equip./Engineering Controls/Physical Form	% new substance	% in Formulation	CBI
(1)	(2)	(3)	(4a)	(4b)	(5)	(6)	(6)	(7)	(8)
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X

Release Number	Amount of New Substance Released		CBI	Media of Release & Control Technology	CBI
(9)	(10a)	(10b)	(11)	(12)	(13)
XXX	XXX	XXX	X	Air / Fume Capture, Thermal oxidizer	
XXX	XXX	XXX	X	Air/Off site drum recycle / incinerate residue	
XXX	XXX	XXX	X	air/Off site Waste Incinerator	
XXX	XXX	XXX	X	Air/Off site Waste incinerator	
XXX	XXX	XXX	X	Solid Waste / Sanitary Landfill (encapsulated in polymer)	

Mark (X) this box if the data continues on the next page. ☐

(14) Byproducts: | **(15) CBI** ☐

Enter Attachment filename for Part II, Section B. ☐

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in the following section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, and/or raw materials substitution. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Quantitative or qualitative descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction in addition to compliance with existing regulatory requirements. The EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other media (e.g., air to water) or nonenvironmental areas (e.g., occupational or consumer exposure). To the extent known, information about the technology being replaced will assist EPA in its relative risk determination. In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

Describe the expected net benefits, such as

(1) an overall reduction in risk to human health or the environment;
(2) a reduction in the generation of waste materials through recycling, source reduction or other means;
(3) a reduction in the use of hazardous starting materials, reagents, or feedstocks;
(4) a reduction in potential toxicity, human exposure and/or environmental release; or
(5) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

Information provided in this section will be taken into consideration during the review of this substance. See PMN Instructions Manual and Pollution Prevention Guidance manual for guidance and examples.

-highly efficient FR that allow lower dosage and thus preserve better material properties of the treated polymer (e.g., films with better impact resistance and elongation values, transparency of treated films can be retained)
-halogen-free alternative to the organic halogenated FR currently used in films (include medium or long-chained chlorinated paraffins, Hexabromocyclododecane, Decabromodiphenyloxide, Decabromodiphenylethane, Tris (bromoneopentyl) phosphate; usually combined with antimony trioxide as synergist)
- little potential for bioaccumulation (especially when compared to organic brominated compounds)
- less release of corrosive gases in the event of a fire
- generally lower smoke toxicity (CO) in the event of a fire
- lower smoke density in the event of a fire

Enter Attachment filename for Pollution Prevention Page 11.		☐

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form, test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of any paper attachments. In the Number of Pages column below, enter the inclusive page numbers of each attachment for paper submissions or enter the total number of pages for each attachment for electronic submissions. Electronic attachments can be identified by filename.
Mark (X) the "Confidential" box next to any attachment name or filename you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

#	Attachment Name	Attachment Filename	Number of Pages	Associated PMN Section Number	CBI
001	Aflammit PCO 700 Label	PC700_label.pdf	1		
002	Aflammit PCO 700 MSDS	PCO700_MSDS.pdf	7		
003	Aflammit (Flammentin) PCO 700 Data	DATA-PCO700_Sanitized.pdf	1		
004	Aflammit (Flammentin) PCO 700 Data	emissmodel_Sanitized.pdf	5		
005	Aflammit (Flammentin) PCO 700 Data	partsize_Sanitized.pdf	4		
006	Aflammit (Flammentin) PCO 700 Data	studyindex_Sanitized.pdf	2		
007	Aflammit (Flammentin) PCO 700 Data	1150_Sanitized.pdf	46		
008	Aflammit (Flammentin) PCO 700 Data	1252_Sanitized.pdf	21		
009	Aflammit (Flammentin) PCO 700 Data	1253_Sanitized.pdf	22		
010	Aflammit (Flammentin) PCO 700 Data	1254_Sanitized.pdf	27		
011	Aflammit (Flammentin) PCO 700 Data	1255_Sanitized.pdf	23		
012	Aflammit (Flammentin) PCO 700 Data	CHEMICAL	1	Pt.I, Sec.B, 1e.	
013	Aflammit (Flammentin) PCO 700 Data	Warehouse Locations_Sanitized.pdf	1	Pt.2, Sec.B, 1a.	

Mark (X) this box if the data continues on the next page. ☐

PMN Page 13

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

The information on this page refers to chemical number(s): ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. Give the attachment number (found on page 12) in column (b). The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in __). You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify the review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)		Unit	Mark X if Provided	Attachment Number (b)	Value (c)			Measured or Estimate (M or E)	CBI Mark (X) (d)
					(solid)	(liquid)	(gas)		
Physical state of neat substance			☐		X	☐	☐	Measured	
Vapor Pressure @ Temperature	20	°C	☐		0.232		Torr	Measured	
Density/relative density			☐		XXX		g/cm3		X
Solubility			☐		243		g/L	Measured	
@ Temperature	20	°C							
Solvent	Water								
Solubility in Water @ Temperature	20	°C	☐		243		g/L	Measured	
Melting Temperature			☐		XXX		°C		X
Boiling / Sublimation temperature @		Torr	☐		N/A		°C		
Spectra			☐						
Dissociation constant			☐						
Octanol / water partition coefficient			☐		XXX				X
Henry's Law constant			☐						
Volatilization from water			☐						
Volatilization from soil			☐						
pH@ concentration	100g/L		☐		8.5			Measured	
Flammability			☐		Not Flammable			Measured	
Explodability			☐		none			Measured	
Adsorption / Coefficient			☐						
Particle Size Distribution			☐		XXX			XXX	X
Other – Specify			☐						

ATTACHMENT HEADER SHEET

Attachment Number 001

Attachment Name

Aflammit PCO 700 Label

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 002

Attachment Name

Aflammit PCO 700 MSDS

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 003

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 004

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 005

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 006

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 007

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 008

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 009

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 010

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 011

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

N/A

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 012

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

Pt.I, Sec.B, 1e.

Does not contain CBI

Report Number

31AU101012165639379

ATTACHMENT HEADER SHEET

Attachment Number 013

Attachment Name

Aflammit (Flammentin) PCO 700 Data

Associated PMN Section Number

Pt.2, Sec.B, 1a.

Does not contain CBI

Report Number

31AU101012165639379

THOR

August 2, 2011

Loraine Passe
Program Manager
US Environmental Protection Agency
EPA East Building
Room 4133L
1201 Constitution Ave, NW
Washington, DC 20004

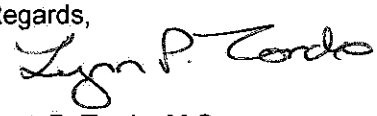
Re: PMNs P11-49 and P11-50

Dear Ms. Passe,

Please find enclosed one signed copy of the section 5(e) Consent Order for the above-referenced premanufacture notices (PMNs).

We trust this paperwork is satisfactory. Please do not hesitate to contact me if you need anything further.

Regards,



Lynn P. Tordo, M.S.
Regulatory Manager
ltordo@thorsp.com

Cc: Thomas Mueller, Thor GmbH (via email)

THOR SPECIALTIES, INC.
56 Quarry Road · Trumbull, CT 06611 · U.S.A.
Telephone: (203) 365-6530 · Fax: (203) 365-6537
Email: info@thorsp.com

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
Thor Specialties, Inc.	)	P11-49 and P11-50
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMNs") P11-49 and P11-50 for the chemical substances: [redacted] (P11-49) and [redacted] (1:1) (P11-50) ("the PMN substances") submitted by Thor Specialties, Inc. ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

- submit to EPA certain toxicity testing at least 14 weeks before manufacturing or importing a combined total of [redacted] kilograms (Tier 1) and [redacted] kilograms of the PMN substances (Tier II);
- provide its workers personal protective equipment to prevent dermal exposure;
- provide its workers respirators with an Assigned Protection Factor (APF) of 10 or greater to

prevent inhalation exposure;

- as an alternative to using respirators, maintain workplace airborne concentrations of the PMN substances at or below specified New Chemical Exposure Limits ("NCELs"), equal to 3.5 mg/m^3 for P11-49 and equal to 10 mg/m^3 for P11-50, verified by actual exposure monitoring data (to pursue this option, a sampling and analytical method must be developed by the Company, verified by an independent third-party laboratory, and submitted to EPA);

- label the PMN substances and provide Material Safety Data Sheets ("MSDS") and worker training in accordance with the provisions of the Hazard Communication Program section;

- distribute the PMN substances only to a person who agrees to follow the same restrictions (except the testing requirements) and to not further distribute the PMN substances until it has been completely reacted; and

- maintain certain records.

III. CONTENTS OF PMN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims for P11-49 and P11-50 (Bracketed in the Preamble and Order): Chemical Identities, production volumes, processing and use information, other information

Chemical Identities:

Specific: P11-49 [redacted]; P11-50 [redacted]

Generic: P11-49 and P11-50 Alkyl phosphonic acid amine salt

Use:

Specific: P11-49 and P11-50: [redacted]

[redacted].

Generic: P11-49 and P11-50: Flame retardant for incorporation into polymer resins (open non-dispersive use).

Maximum 12-Month Production Volumes: P11-49 [redacted] kilograms/year and P11-50 [redacted] kilograms/year

Test Data Submitted with PMNs:

Human Health:

P11-49:

Negative in Salmonella with and without activation;
Negative for chromosome aberration in V79 cells, with and without activation;
Negative in mouse lymphoma mutagenicity assay;
Rat (F) oral (gavage) LD50 > 2000 milligrams/kilograms (mg/kg);
Rat dermal LD50 > 2000 mg/kg;
Not a dermal irritant in rabbits;
Slight eye irritant in rabbits;
Not a dermal sensitizer in female mice;
Rat 28-day oral (gavage) No Observable Adverse Effect Level (NOAEL) 50 mg/kg, with effects to the kidney at 150 and 1000 mg/kg,
and to the liver and adrenal gland at 1000 mg/kg
Fish 96 hour LC50 >100 parts per million (ppm); daphnia 48-hour LC50 66.3 ppm; green algae 96-hour EC50 > 100 ppm.

P11-50:

Negative in Salmonella with and without activation;
Negative for chromosome aberration in V79 cells with activation, positive without activation;
Negative for chromosome aberration in rat bone marrow cells;
Rat (F) oral (gavage) LD50 > 2000 mg/kg;
Rat dermal LD50 > 2000 mg/kg;

Not a dermal irritant in female rabbits;
Slight to moderate eye irritant in female rabbits, effects cleared by 72 hours;
Not a dermal sensitizer in female mice;
Rat 28-day oral (gavage) NOAEL 150 mg/kg, with effects to the kidney and testes at 1000 mg/kg
Fish 96 hour LC50 >100 parts per million (ppm); daphnia 48-hour LC50 >100 ppm; green algae 96-hour EC50 > 100 ppm.

IV. EPA'S ASSESSMENT OF RISK

The following are EPA's predictions regarding the probable human and environmental toxicity and human exposure, based on the information currently available to the Agency.

Ecotoxicity:

The aquatic acute base-set was conducted on P11-49 and P11-50. The concentration of concern (CoC) for P11-49 is = 636 µg/L (ppb) and the CoC for P11-50 = 1000 µg/L (ppb). Estimated releases to water for the chemicals do not exceed the CoCs.

Human Health Effects Summary:

Absorption: For both PMNs, absorption is nil through the skin based on physical/chemical properties, and good through the lung and GI tract based on analogs.

Immunotoxicity:

Based on the ethylenediamine, P11-49 is considered a moderate respiratory and dermal sensitizer. A mouse local lymph node assay was conducted on this PMN that showed no sensitizing effects; however, because of the ethylenediamine, P11-0049 is considered to be a respiratory sensitizer. Data submitted to EPA on ethylenediamine, tested both as the free base and various salts, demonstrated that ethylenediamine is a dermal sensitizer in guinea pigs (in both the Buehler and Magnusson-Kligman Maximization tests) and in human patch tests,

although the study on the PMN on rabbits did not show dermal irritation.

Reproductive/Developmental Toxicity:

There is no reproductive or developmental data on the PMN substances themselves, but studies on ethylenediamine (P11-49 cationic component) and melamine (P11-50 cationic component) indicate potential for reproductive and developmental effects. In general, the LOAEL's and NOAEL's from these studies were higher than those derived from the rat 28-day subchronic studies of the PMNs themselves. Thus, the NOAELs used for this risk assessment are based on the 28-day rat oral toxicity studies (based on the 28-day study, the NOAEL for P11-49 is 50 mg/kg-day and the NOAEL for P11-50 is 150 mg/kg-day).

Exposure Summary:

	Process P11-49	Use P11-49	Process P11-50	Use P11-50
# Sites	[redacted]	[redacted]	[redacted]	[redacted]
Workers (total)	[redacted]	[redacted]	[redacted]	[redacted]
Exposure (days/year)	[redacted]	[redacted]	[redacted]	[redacted]
Dermal Exposure (mg/day)	3100	470	3100	470
Inhalation Exposure (mg/day)	150	22	150	22

Risk to Workers:

A margin of exposure (MOE) of 100 or greater indicates no adverse effects would be likely to occur under the assumed exposure conditions. The MOEs for P11-49 and P11-50 are 23 and 70, respectively. The MOEs were derived from potential inhalation exposures during the processing operation of plastic compounding. The calculated inhalation MOEs during use and

the dermal MOEs during processing and use were over 100.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for reproductive and developmental effects from exposure to P11-49 and P11-50 and dermal sensitization from exposure to P11-49. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health effects of the PMN substances.

(b) In light of the potential risk of reproductive and developmental effects from exposure to P11-49 and P11-50 and dermal sensitization from exposure to P11-49, posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances may present an unreasonable risk of injury to human health.

VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding specified production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The following additional information would be required to evaluate the following effect which may be caused by the PMN substance P11-49:

Effect	Guideline
Dermal sensitization potential for P11-49	Buehler or Magnusson-Kligman Maximization test with guinea pigs; OCSPP 2600 or OECD 406

The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substances P11-49 [redacted] and P11-50 [redacted] ("the PMN substances") in the United States by Thor Specialties, Inc.("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substances is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substances after they have been completely reacted (cured).

(2) De Minimis Concentrations. The requirements of this Order do not apply to quantities of the PMN substances that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substances is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substances in the mixture may be re-concentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(3) Export. Until the Company begins commercial manufacture of the PMN substances for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in

the Testing section of this Order.

(4) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(5) Byproducts. The requirements of this Order do not apply to the PMN substances when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(6) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substances, mixture, or article of which it is a part.

(7) Imported Articles. The requirements of this Order do not apply to the PMN substances when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably supports the conclusion that the PMN substances presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for this substances and contain a statement that the substances is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tsca8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following

information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substances and a statement that the substances is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any such study, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing or importing the PMN substances beyond the following aggregate manufacture and import volumes ("the production limits"), unless the Company conducts the following studies on the PMN substances and submits all final reports and underlying data in accordance with the conditions

specified in this Testing section.

Production Limit (kilograms)	Study	Guideline
Tier 1: 161,000	a combined repeated dose oral study combined with a reproductive /developmental screen	OCSPP 870.3650 or OECD 422.
Tier II: 584,000	90-day inhalation study in rats and mice with a 4-week recovery period.	OCSPP 870.3465 or OECD 413.

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will not require the submission of raw data such as slides and laboratory notebooks unless if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substances beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the

Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the

Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substances, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the

Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substances at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substances), the Company must establish a program whereby:

(1) General Dermal Protection. Each person who is reasonably likely to be dermally exposed in the work area to the PMN substances through direct handling of the substances or through contact with equipment on which the substances may exist, or because the substances becomes airborne in a form listed in subparagraph (a)(4) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substances in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and

Health Administration ("OSHA") dermal protection requirements at 29 CFR 1910.132, 1910.133, and 1910.138.

(2) Demonstration of Imperviousness. The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area. Permeation testing shall be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Resistance of Protective Clothing materials to Permeation by Liquids or Gases." Results shall be recorded as a cumulative permeation rate as a function of time, and shall be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99 "Guide for Documenting the Results of Chemical Permeation Testing on Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substances.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substances alone and in likely combination with other chemical substances in the

work area.

(3) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substances in the form listed in subparagraph (a)(4) of this section, is provided with, and is required to wear, at a minimum, a National Institute for Occupational Safety and Health ("NIOSH")-certified respirator with an Applied Protection Factor ("APF") of 10, from the respirators listed in subparagraph (a)(5) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 CFR 1910.134.

(4) Physical States. The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (3) of this section:

(i) Particulate (including solids or liquid droplets),

(5) Authorized Respirators. The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(3) of this section:

(i) Particulate/Aerosol/Mist Exposures, APF of 2 to 10:

(I) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(II) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.

(III) NIOSH-certified powered air-purifying respirator equipped with a loose- fitting hood or helmet and high efficiency particulate air ("HEPA") filters.

(IV) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters.

(V) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

NEW CHEMICAL EXPOSURE LIMITS

(a) Alternative to Requirements of Respirator Section.

(1) EPA recommends and encourages the use of pollution prevention, source reduction, engineering controls and work practices, rather than respirators, as a means of controlling inhalation exposures whenever practicable.

(2) Whenever a person is reasonably likely to be exposed to the PMN substances by inhalation, as an alternative to compliance with the respirator requirements in the Protection in the Workplace section of this Order, the Company may comply with the requirements of this New Chemical Exposure Limit section. However, before the Company may deviate from the respirator requirements in the Protection in the Workplace section of this Order, the Company must:

(i) submit to EPA a copy of the Company's sampling and analytical method for the PMN substances, verified in accordance with subsection (c)(3) of this New Chemical Exposure Limit section;

(ii) obtain exposure monitoring results in accordance with this New Chemical Exposure Limit section; and

(iii) based on those exposure monitoring results, select, provide, and ensure use if necessary of the appropriate respiratory protection specified in paragraph (e)(2) of this New

Chemical Exposure Limit section by persons who are reasonably likely to be exposed to the PMN substances by inhalation.

(3) After appropriate respiratory protection has been selected at a workplace based on the results of actual exposure monitoring conducted in accordance with this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required in the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section).

(b) Exposure Limit.

(1) General. The following new chemical exposure limit ("NCEL") for the PMN substances is an interim level determined by EPA based on the limited information available to the Agency at the time of development of this Order. The NCEL for the PMN substances is as follows:

(i) Time-Weighted Average ("TWA") Limit. The Company shall ensure that no person is exposed to an airborne concentration of the PMN substances in excess 3.5 mg/m^3 for P11-49 and 10 mg/m^3 for P11-50 ("the NCELs") as an 8-hour time-weighted average, without using a respirator in accordance with subsection (e) of this New Chemical Exposure Limit section.

(ii) Non-8-Hour Work-shifts. For non-8-hour work-shifts, the NCEL for that work-shift (NCELn) shall be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift.

(2) Automatic Sunset. If, subsequent to the effective date of this Order, OSHA promulgates, pursuant to §6 of the Occupational Safety and Health Act, 29 U.S.C. 655, a final

chemical-specific permissible exposure limit ("PEL") specifically applicable to this PMN substances and the OSHA PEL is not challenged in court within 60 days of its promulgation, then any respirator requirements in the Protection in the Workplace section of this Order and any requirements of this New Chemical Exposure Limit section applicable to workers and situations subject to the OSHA PEL shall automatically become null and void. However, the requirements of this Consent Order are not negated by any pre-existing OSHA PEL applicable to the PMN substances.

(c) Performance-Criteria for Sampling and Analytical Method.

(1) Applicability. For initial development and validation of the sampling and analytical method for the PMN substances, all the requirements of this subsection (c) apply. For subsequent exposure monitoring conducted pursuant to subsection (d) of this New Chemical Exposure Limit section, only the following requirements apply: (c)(4)(i), (4)(ii), (4)(iv)(B), (4)(v)(B), (8), (9), and (10). Any deviation from the requirements of this subsection (c) must be approved in writing by EPA.

(2) Submission of Verified Method and Certification Statement. The Company shall submit to EPA a copy of a validated sampling and analytical method for the PMN substances which satisfies the criteria specified in this subsection (c). The method description shall expressly state how the method compares with each quantitative requirement specified in this subsection (c). The submission must include a written statement, signed by authorized officials of both the Company and the Laboratory, certifying the truth and accuracy of the independent laboratory verification conducted pursuant to subsection (c)(3). To assist EPA in identifying the

document, it shall state in a conspicuous, underlined subject-line at the top of the first page: "NCEL Sampling and Analytical Method for PMN #_____," after-which the correct PMN number for the chemical substance shall be stated.

(3) Verification of Analytical Method by Independent Third-Party Laboratory.

(i) Verification. The Company shall have an independent reference laboratory ("Laboratory") verify the validity of the analytical method for the PMN substances, in accordance with the other requirements in this subsection (c)(3). It is the Company's responsibility to ensure that the Laboratory complies with all the requirements specified in this subsection (c)(3).

(ii) Independent Reference Laboratory. The independent reference laboratory must be a separate and distinct person (as defined at 40 CFR 720.3(x)) from the Company and from any other person who may have developed the method for the Company.

(iii) Accreditation. The Laboratory must be accredited by a formally recognized government or private laboratory accreditation program for chemical testing and/or analysis.

(iv) Good Laboratory Practice Standards. The Laboratory verification of the analytical method for the PMN substances must comply with TSCA Good Laboratory Practice Standards ("GLPS") at 40 CFR Part 792. [Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required under this New Chemical Exposure Limit section where the analytical method is verified by a laboratory accredited by either: (A) the American Industrial Hygiene Association

("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(v) Analysis of Duplicate Samples. The Company shall collect six duplicate samples (a total of 12) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. The duplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company, the other set of six samples shall be analyzed by the Laboratory using the method developed by or for the Company.

(vi) Sample Storage Study. If the results of the analysis of duplicate samples pursuant to paragraph (c)(3)(v) do not satisfy the requirements in paragraph (c)(3)(vii), the Company must perform a sample storage study as follows:

(I) Triplicate Samples. The Company shall collect six triplicate samples (a total of 18) at the TWA concentration. The samples shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. The triplicate samples shall be collected on identical collection media, at the same time, and under the same conditions. One set of six samples shall immediately be analyzed by the Company.

(II) Analysis After Sample Storage. A sample storage evaluation shall be performed with the two remaining sets of six samples. One set of six samples shall be analyzed

by the Laboratory using the method developed by or for the Company, and the other shall be analyzed by the Company on the same day as the Laboratory analyzes its six samples. Specialized storage conditions for the samples including extraction conditions, time from sampling to extraction, time from collection or extraction (if applicable) to analysis and storage conditions must be specified in the method description.

(vii) Comparison of Results. The difference between the results of the two sets of six samples analyzed by the Laboratory and the Company as required in either paragraph (c)(3)(v) or (c)(3)(vi)(II) shall be evaluated using a two-sample t-test with unequal variances, and the two sides of the critical regions shall not exceed a 5% significance level. (See Attachment B - Statistical Analysis of NCELs Analytical Method Verification Results.) The arithmetic mean of each set of six samples must be within 10% of the overall arithmetic mean of the two sets of sample measurements. If the arithmetic mean of each set of six samples is not within 10% of the overall arithmetic mean, then the sample storage time between collection and analysis must be reduced until the average of each set of six samples is within 10% of the overall arithmetic mean.

(4) Accuracy. The sampling and analytical method must clearly demonstrate the following:

(i) General. The sampling and analytical method, and all exposure monitoring data relied on by the Company, shall be accurate to within ±25% at a 95% confidence level for concentrations of the PMN substances ranging from one half the NCEL to twice the NCEL.

(ii) NCEL Quantitation Limits. The analytical method should be capable of reliably quantifying the PMN substances across the full range of reasonably likely exposures. At a minimum, the analytical method must be capable of reliably quantifying from a lower

quantitation limit ("LQL") of one half the NCEL to an upper quantitation limit ("UQL") of at least twice the NCEL. If the Company obtains an exposure monitoring sample that is more than 10% above the actual UQL of the analytical method, the Company must comply with paragraph (e)(4)(i).

(iii) Lower Quantitation Limit Signal-To-Noise Ratio. The analytical method shall be capable of quantifying the PMN to a concentration of one half the NCEL with a signal that is at least five times the baseline noise level. Baseline noise must be amplified to a measurable level when possible, even if the required amplification is beyond that used in routine analysis of samples. (If baseline noise cannot be obtained, another reference must be selected. This may be a peak considered to be noise caused by the reagent matrix.) The sampling preparation method must be specified and the detection limit for the analytical procedure must be reported as mass per injection for chromatographic techniques.

(iv) Instrument Calibration.

(I) Initial Calibration. For method development and validation (but not subsequent exposure monitoring), the initial calibration shall at a minimum consist of five (5) calibration standards with a linear correlation of 0.95 -- these five (5) calibration standards must consist of one standard at each of the following concentrations: one half the NCEL (0.5 x NCEL); between one half and one times the NCEL (0.5 x NCEL < > 1 x NCEL); one times the NCEL (1 x NCEL); between one and two times the NCEL (1 x NCEL < > 2 x NCEL), and twice the NCEL (2 x NCEL).

(II) Continuing Calibration. During each week of both method development/validation and subsequent exposure monitoring, the Company shall conduct both

an initial instrument calibration and a continuing calibration. The Company shall perform at least one continuing calibration sample at the NCEL concentration, and at least one additional calibration sample per every 10 samples analyzed. The continuing calibration sample shall fall within ± 25% of the initial calibration value. If not, then the initial calibration must be repeated, and any samples associated with that outlying calibration check must be re-analyzed.

(v) Calculated Percent Recovery.

(I) Initial Calculation. For method development and validation, the Company must calculate the percent of the PMN substances recovered by the analytical method from a sample containing a known quantity of the PMN substances. The sample shall be taken either from a controlled environment (e.g., a sealed chamber or "glove box") which closely resembles the actual workplace conditions or, for solids and liquids with very low vapor pressure, by injecting the PMN substances onto a sample collection device. (Such a sample is referred to as a "matrix spike"). The calculated percent recovery for each matrix spike shall be greater than or equal to 75% and less than or equal to 125%. Spike concentrations for the PMN substances must be included in the sampling and analytical method submitted to EPA.

(II) Subsequent Calculation. During each subsequent exposure monitoring episode or campaign, at least 1 matrix spike, prepared by injecting the PMN substances onto a sample collection device, shall be analyzed. (This matrix spike must be prepared at the NCEL concentration.)

(vi) Sampling Device Capacity. The capacity of the sampling device must be tested and results reported to show under a known and well-defined set of conditions that the device is capable of collecting the new chemical in solid, liquid or vapor phase with minimal

loss. The sampling device's capacity (air volume and collected analyte mass) must be specified. For methods that use adsorbent tubes as the collection medium, evidence of the capacity must be provided in the form of breakthrough testing. This testing must be done at a concentration twice the NCEL and under conditions similar to those expected in the workplace. Breakthrough is defined to have occurred when the concentration of the PMN substances in the effluent stream is equal to 5% of the concentration of the influent stream, or when 20% of the PMN substances is detected in the backup section of the sampler.

(vii) Sampling Device Desorption Efficiency. Where applicable, the desorption efficiency must be evaluated for the air sampling device. A minimum of six air samples spiked with the PMN substances at least the NCEL concentration must be prepared. A recovery of at least 75% must be obtained for each of the six samples.

(5) Precision. The estimate of the coefficient of variation of each set of six samples from the controlled atmosphere test (spiked at 1.0 NCEL, per paragraphs (c)(3)(v) or (vi)) must be less than 0.105, including allowance of 0.05 for error due to sampling.

(6) Interpretation of Accuracy and Precision Data.

(i) If a single matrix spike recovery is less than 75% recovery or greater than 125% or the estimated precision is greater than 0.105, then the Company must re-prepare the matrix spike, re-sample, and re-analyze all samples associated with such matrix spike or triplicate samples.

(ii) For percent recoveries less than 90% but greater than 75%, correction for low recovery is required. Correct for recovery first by dividing the observed amount by the proportion recovered before determining if measurements fall below the NCEL. For example, if

the observed level is 30 mg/m^3 and the percent recovery is 75%, use the value 30 mg/m^3/(0.75) = 40 mg/m^3 when determining whether the levels are below the exposure limit.

(7) Representativeness. All sample conditions used to develop the methodology shall mimic the actual workplace environment expected to be monitored. Conditions such as the temperature, humidity, lighting, and presence of other chemicals, etc. must mimic the conditions in the workplace to be monitored.

(8) Changes Affecting Validity. If the workplace environment changes from the initial conditions described in the verified sampling and analytical method in a way reasonably likely to invalidate the accuracy of the method, then the Company must comply with the respirator requirements in the Protection in the Workplace section of this Order, unless the Company re-validates the method to confirm that the requirements for accuracy and precision in paragraphs (c)(4) and (5) are met. Examples of possible changes include but are not limited to: introduction of a new chemical substances to the workplace which may interfere with the analysis of the new chemical; introduction of light to the workplace which may interfere with a light-sensitive PMN substances; or introduction of water/increased humidity to the workplace which could react with the PMN substances and cause difficulties in collection and analysis.

(9) Comparability. All data and results shall be reported in the same units of measurement as the NCEL.

(10) Responsibility for Method Validity. The independent laboratory verification and EPA receipt of the sampling and analytical method pursuant to this subsection (c) do not ensure that the method will produce valid exposure monitoring data. The Company is ultimately responsible for ensuring the validity of its exposure monitoring data.

(d) Monitoring Potential Exposure.

(1) General.

(i) Action Level. The "action level" is defined as an airborne concentration of the PMN substances, calculated as an 8-hour time-weighted average, equal to one half the NCEL TWA specified in subparagraph (b)(1). For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in subparagraph (b)(1)(ii).) The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

(ii) Representative Exposure Groups. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company shall take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the PMN substances would be if respirators were not worn. The Company shall do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an "exposure group") where inhalation exposure to the PMN substances is reasonably likely to occur. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

(iii) Good Laboratory Practice Standards. Determinations of potential inhalation exposure shall be made according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the sampling and analytical method developed pursuant to subsection (c) of this New Chemical Exposure Limit section. [Certain provisions of the TSCA GLPS applicable to toxicity

testing in laboratory animals, such as 40 CFR 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.] However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP"); or (B) another comparable program approved in advance in writing by EPA.

(iv) Full Shift Exposure Samples. Representative 8-hour TWA airborne concentrations shall be determined on the basis of samples representing the full shift exposure for each exposure group.

(2) Initial Monitoring. Before the Company may deviate from the respirator requirements of the Protection in the Workplace section, the Company shall conduct initial exposure monitoring to accurately determine the airborne concentration of the PMN substances for each exposure group in which persons are reasonably likely to be exposed to the PMN substances.

(3) Periodic Monitoring.

(i) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 6 months. If the PMN substances is not manufactured, processed, or used at all during a given 6 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substances is resumed. However, cessation of manufacturing, processing and use of the PMN substances for less than the 6 month period does not constitute grounds for postponement of the 6 month deadline to conduct exposure monitoring.

(ii) If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company shall repeat the exposure monitoring for that exposure group at least every 3 months. If the PMN substances is not manufactured, processed, or used at all during a given 3 month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the PMN substances is resumed. However, cessation of manufacturing, processing and use of the PMN substances for less than the 3 month period does not constitute grounds for postponement of the 3 month deadline to conduct exposure monitoring.

(iii) The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the PMN substances is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(4) Termination of Monitoring.

(i) If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section.

(ii) If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days

apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by paragraph (d)(5) of this New Chemical Exposure Limit section. Where the PMN substances is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

(5) Additional Monitoring.

(i) For a previously monitored exposure group, the Company shall, within 7 days of any of the events listed below in this paragraph (d)(5)(i), conduct the initial exposure monitoring followed by any periodic or additional exposure monitoring required by subsection (d) of this New Chemical Exposure Limit section:

(I) change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the PMN substances;

(II) spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the PMN substances; and,

(III) whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the PMN substances.

(ii) In no event is the additional exposure monitoring requirement in paragraph (d)(5)(i) intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing additional exposure monitoring, the Company shall ensure that potentially exposed persons use at least the respiratory protection specified in subsection (e) for the measured airborne concentration, or more

protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(6) Notification of Monitoring Results.

(i) Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company shall notify each person whose exposure is represented by that monitoring. The notice shall identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by subsection (e). Affected persons shall be notified in writing either individually or by posting the information in an appropriate and accessible location.

(ii) Whenever the NCEL is exceeded, the written notification required by the preceding paragraph shall describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or shall refer to a document available to the person which states the actions to be taken to reduce exposure.

(7) Exemption based on Objective Data. Where the Company has documented and reliable objective data demonstrating that, even under worst-case conditions, employee exposure to the PMN substances will not exceed the action level (defined in paragraph (d)(1)(i)) under the expected handling procedures and conditions for a specific "exposure group" (defined in paragraph (d)(1)(ii)), then that exposure group is exempt from this New Chemical Exposure Limit section (except paragraph (d)(5) "Additional Monitoring" and subsection (f) "NCEL Record-keeping") and the respirator requirements in the Protection in the Workplace section of this Order. Any such objective data must accurately characterize actual employee exposures to the PMN substances and must be obtained under conditions closely resembling the types of materials,

processes, control methods, work practices, and environmental conditions in the Company's current workplace operations with the PMN substances. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the PMN substances, industry-wide studies, and/or laboratory test results.

(e) Respiratory Protection.

(1) General. Whenever the Company has conducted exposure monitoring at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section and the measured airborne concentration of the PMN substances for any person who is reasonably likely to be exposed to the PMN substances by inhalation exceeds the NCEL, the Company shall provide those persons the respirators specified in this subsection (e) (rather than the respirator(s) identified in the Protection in the Workplace section of this Order), and shall ensure that the respirators are used (including training, fit testing, and maintenance) in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. When the Company has not yet measured the airborne concentration of the PMN substances at a workplace in accordance with this New Chemical Exposure Limit section, the Company shall comply with the respirator requirements in the Protection in the Workplace section of this Order at that workplace.

(2) Selection of Appropriate Respiratory Protection. After the Company has conducted exposure monitoring in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall select, provide, and ensure that persons who are reasonably likely to be exposed to the PMN substances by inhalation use, at a minimum, the respiratory protection which

corresponds in the following table to the measured airborne concentration (or a more protective respirator which corresponds to a concentration higher than measured).

PARTICULATE RESPIRATOR TABLE

Measured Concentration of PMN Substance	Required Respiratory Protection
≤ NCEL	▶ No respiratory protection is required.
≤ 10 x NCEL	▶ NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. ▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. ▶ NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air ("HEPA") filters. ▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).
≤ 25 x NCEL	▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. ▶ NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and HEPA filters. ▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

≤ 50 x NCEL	▶ NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. ▶ NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters. ▶ NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece (either half-face or full-face).
≤ 2000 x NCEL	▶ NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece.
> 2000 x NCEL	▶ Any self-contained respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode. ▶ Any supplied-air respirator equipped with a full facepiece operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.

(3) Reductions in Respiratory Protection. After appropriate respiratory protection has been selected based on the results of actual exposure monitoring conducted at a workplace in accordance with subsection (d) of this New Chemical Exposure Limit section, the Company shall not, at that workplace, use the respiratory protection required by the Protection in the Workplace section of this Order (unless it is the same as required by this New Chemical Exposure Limit section). Before the Company may make any reduction in any respiratory protection selected pursuant to this New Chemical Exposure Limit section, the Company must verify, by 2 consecutive measurements taken at least 7 days apart, that the new respiratory protection is appropriate in accordance with paragraph (e)(2). Where the PMN substances is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak

exposures and variability in exposure.

(4) Special Situations.

(i) Measurements Outside Quantitation Limits. When a value less than the lower quantitation limit ("LQL") of the analytical method (as described in paragraph (c)(4)(ii)) is measured, the Company shall estimate potential exposure using generally established and accepted statistical methods. If the Company obtains an exposure monitoring sample that is more than 10% above the actual upper quantitation limit ("UQL") of the analytical method, the Company must ensure that its workers wear at least a NIOSH-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece. Any reductions in this respiratory protection must comply with paragraph (e)(3). The Company may submit an improved analytical method provided that it complies fully with subsection (c) of this New Chemical Exposure Limit section, including the verification required by subsection (c)(3).

(ii) Cleanup and Remedial Actions. During any special cleanup or other remedial actions that may occur before commencing additional exposure monitoring (as discussed in paragraph (d)(5)(ii)), the Company shall ensure that potentially exposed persons use at least the respiratory protection specified above in this subsection (e) for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

(f) NCEL Recordkeeping.

(1) Whenever the Company elects to comply with this New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this

Order, the Company shall maintain the following records until 30 years after the date they are created, and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(i) A copy of the sampling and analytical methods used and continuing evidence of their accuracy over time as required by section (c);

(ii) Records documenting compliance with the analytical method verification requirements of subsection (c)(3), including copies of the signed certification statement and the verification results obtained by both laboratories;

(iii) Records documenting either compliance with the Good Laboratory Practice Standards at 40 CFR Part 792, or use of a laboratory accredited by the American Industrial Hygiene Association ("AIHA") or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records shall include the written accreditation from the AIHA or the written approval from EPA.

(iv) Records documenting all exposure monitoring dates, duration, and results of each sample taken;

(v) Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;

(vi) Any conditions that might have affected the monitoring results;

(vii) Notification of exposure monitoring results required by paragraph (d)(6);

(viii) Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to

the PMN substances;

(ix) Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;

(x) The type of respiratory protective devices worn by the monitored person, if any;

(xi) Records documenting any actions taken to mitigate exposures to the PMN substances;

(xii) Records documenting reliance on the objective data exemption in paragraph (d)(7), including: (A) the source of the data, (B) protocols and results of any relevant testing or analysis, (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level, (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substances in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall

include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 C.F.R. Part 721, subpart E. The list must be maintained in each work area where the PMN substances is known to be present and must use the identity provided on the MSDS for the substances required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substancess, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substances (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substances contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substances in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substances while in the Company's workplace.

(b) Labeling.

(1) The Company shall ensure that each container of the substances in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(I) A statement of the health hazards(s) and precautionary measure(s), if

any, identified in paragraph (f) of this section or by the Company, for the PMN substances.

(II) The identity by which the PMN substances may be commonly recognized.

(III) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Company, for the PMN substances.

(IV) A statement of exposure and precautionary measure(s), if any, identified in paragraph (f) of this section, or by the Company, for the PMN substances.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substances is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substances obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substances leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(I) The information prescribed in subparagraph (b)(1)(i) of this section.

(II) The name and address of the manufacturer or a responsible party who can provide additional information on the substances for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substances in combination with any other substances that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substances or ways to protect against the hazards, this new information must

be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substances is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substances is reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Company must obtain or develop an MSDS for the PMN substances.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substances under this section, and, if not claimed confidential, the chemical and common name of the PMN substances. If the chemical and common name is claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substances known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substances known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substances known to the Company.

(vi) The primary routes of exposure to the PMN substances.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40

CFR 721.30 provide substantially the same degree of protection as the identified control measures. The MSDS must identify any New Chemical Exposure Limits specified in paragraph (b) of the New Chemical Exposure Limit section of this Order and must contain the information specified in the graduated respirator table in paragraph (e)(2) of the New Chemical Exposure Limit section.

(viii) Any generally applicable precautions for safe handling and use of the PMN substances which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substances and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substances have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the

hazards of the PMN substances or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substances is not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substances is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substances from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substancess in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substancess. However, in all cases, the required information must be provided for the PMN substances and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substances. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN

substances and whenever the PMN substances is introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substances is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substancess required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substances in or from an employee's work area (such as exposure monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substances when being released).

(ii) The potential human health and environmental hazards of the PMN substances as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substances, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substances, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. These substances may cause:

(i) reproductive effects.

(ii) developmental effects.

(2) Human hazard precautionary statements. When using these substances:

(i) avoid skin contact.

(ii) avoid breathing the substances.

(iii) avoid ingestion.

(iv) use respiratory protection, or maintain workplace airborne concentrations at or below an 8-hour time-weighted average of 3.5 mg/m^3 for P11-49 and 10 mg/m^3 for P11-50 (the NCELs).

(v) use skin protection.

(3) The human and environmental hazard and precautionary statement on the label

prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1)

the PMN number, and (2) either (A) the specific chemical identity of the PMN substances, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. (i) Except after the PMN has been completely reacted or as provided in paragraph (c), the Company shall distribute the PMN substances outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substances, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substances to any other person, other than for disposal, until after the PMN substances has been completely reacted (cured).

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace and the New Chemical Exposure Limit sections of this Order.

(4) Comply with the same requirements and restrictions, if any, required of the Company in the Hazard Communication Program section of this Order.

(ii) Disposal Exemption. Except for the §12(b) export notice requirement in paragraph (b)(i)(1) above, the distribution requirements in (b)(i) do not apply when the Company distributes the PMN substances for disposal only.

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substances outside the Company for temporary transport and storage in sealed containers (labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order) provided the following two conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substances may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substances, the Company obtains knowledge that a recipient of the substances has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after paragraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substances (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substances to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this

Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substances and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substances to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR. (1) Paragraph (b)(i)(2) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substances under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraph (b)(i)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substances and paragraph (b)(i)(2) of this

Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substances of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNUR for this PMN substances in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(i)(2), such notice may substitute for the written agreement required in the introductory clause of paragraph (b); so that, if the Company provides such notice to the persons to whom it distributes the PMN substances, then the Company is not required to obtain from such persons the written agreement specified in paragraph (b).

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the Export exemption in Section I, Paragraph (b)(3) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA

sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the Research and Development exemption in Section I, Paragraph (b)(4) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substances, the date of each sale or transfer, and the quantity of the substances sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, import, processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substances;

(7) Records required by paragraph (f) of the New Chemical Exposure Limits section of

this Order, if applicable;

(8) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(9) Copies of labels required under the Hazard Communication Program section of this Order;

(10) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(11) Records documenting compliance with any applicable manufacturing and distribution restrictions in the Manufacturing and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(12) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(13) The Company shall keep a copy of this Order at each of its sites where the PMN substances is manufactured or imported.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of

Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(i) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(v) Records required by the Recordkeeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit

a new PMN to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent

Order and the "Notice of Transfer" document which is incorporated by reference as Attachment C to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances is manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

7/21/11
Date

Maria J. Doa
Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

8/2/2011
Date

Lynn P. Tarda
Name: Lynn P. Tarda
Title: Regulatory Manager
Company: Thor Specialties, Inc.

ATTACHMENT A

DEFINITIONS

Note: The attached Order may not contain some of the terms defined below.

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substances for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substancess of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substances in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substances or any product containing the chemical substances in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substances under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substances is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substances and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substances described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substances or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substances.

"Scientifically equivocal data" means data which, although developed in apparent

conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substances, and from which there will be no human exposure to, or environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

STATISTICAL ANALYSIS OF NCELs ANALYTICAL METHOD VERIFICATION RESULTS

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to paragraph (c)(3)(vii) of the New Chemical Exposure Limit section of this Order.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum(\bar{X}_{ij} - X_i)^2/(n_i - 1),\ i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2)/(W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2/[W_1^2/(n_1 - 1) + W_2^2/(n_2 - 1)]$$

where,

$W_1 = S_1^2/n_1,\ i = 1, 2$

$\bar{X}_1$ = Average of the results from the company laboratory

$\bar{X}_2$ = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the company laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be an integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

Data Set 1	Data Set 2
80.56	97.11
100.01	102.13
86.04	99.83
52.61	97.83
84.85	105.44
95.75	100.04

$\bar{X}_1 = 83.30$ $n_1 = 6$ $\bar{X}_2 = 100.40$ $n_2 = 6$

$S_1^2 = 278.72$ $W_1 = 46.25$ $S_2^2 = 9.26$ $W_2 = 1.54$

Absolute value of T = 2.467 f = 5.33

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T, 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

Data Set 1	Data Set 2
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$\bar{X}_1 = 95.37$	$n_1 = 6$	$\bar{X}_2 = 104.37$	$n_2 = 6$
$S_1^1 = 65.59$	$W_1 = 10.93$	$S_2^2 = 27.25$	$W_2 = 4.54$
Absolute value of T = 2.290		f = 8.54	

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.

ATTACHMENT C

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCESS CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substances, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substancess Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substances, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substances(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCESS CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

TOXIC SUBSTANCESS CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____

Successor's Technical Contact

_____

Address

_____

City, State, Zip Code

_____

Phone

Focus Report

New Chemicals Program

PMN Number: **P-11-0049**

Focus Date:	11/22/2010 12:00:00 AM	Report Status:	Completed
Consolidated Set:			
Focus Chair:	Darlene Jones, Miriam Wiggins-Lewis	Contractor:	Paul Sohi

I. Notice Information

Submitter:	Thor Specialities, Inc.
CAS Number:	[redacted]
Chemical Name:	[redacted]
Use:	Flame retardant [redacted]. Associated Cases Submitted Together: P-11-0049 and P-11-0050. P2REC: CRSS: Forward. P2 Claim: Halogen-free alternative to the organic halogenated flame retardants currently used in films (including medium or long-chained chlorinated paraffins, Hexabromocyclododecane, Decabromodiphenyloxide, Decabromodiphenylethane, Tris(bromoneopentyl)phosphate; usually combined with antimony trioxide as synergist). Little potential for bioaccumulation (especially when compared to organic brominated compounds). [redacted]
Other Uses:	[redacted]
PV-Max:	[redacted] Kg/yr
Manufacture:	Import: X

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 2 **Comments:** ;

Occupational: 2-3C **Non-Occupational:** **Environmental:** 3

(1) **PBT:** 1	1	1	**Comments:**	Anion
(2) **PBT:** 1	1	1	**Comments:**	Cation
(3) **PBT:** 1	1	1	**Comments:**	
(4) **PBT:** 1	1	1	**Comments:**	
(5) **PBT:** 1	1	1	**Comments:**	

III. OTHER FACTORS

Categories:

Health Chemical Category:		Ecotox SAR and Category:	aliphatic amines with molecular weight adjustment; Aliphatic Amines

Related Cases/Regulatory History:

Health related Cases:	
Ecotox Related Cases:	Analog: [redacted]
Regulatory History:	NRC
CRSS P2Rec:	P2Rec-P2 Recognition

MSDS/Label Information:

MSDS:	Yes	Label:	No
General Equipment:	Chemical protective gloves with nitrile rubber, NBR material according to DIN EN 374 with CE-labeling; safety glasses with side shields; protective work clothing		
Respirator:	Put on breathing equipment (Filter P1) if dust develops		
Health Effects:	Non irritant on skin and eye (rabbit); not sensitizing (mouse)		
TLV/PEL (PMN or raw material):	- Not listed with OSHA and NIOSH.		

Exposure Based Information:

Exposure Based Review:	N	Exposure Based Review (Health):	N
Exposure Based Review (Eco):	N	Exposure Based (Occupational):	No
Exposure Based Review		Exposure Based (Environmental):	

(Non Occupatuional):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-11-0049
FATE: Estimations for [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
PMN Substance: Solid
S = [redacted] (M)
VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = Anion 0; Cation 0
Time for complete ultimate aerobic biodeg = Anion da; Cation da-wkwk
Sorption to soils/sediments = Anion low; Cation low
PBT Potential: Anion P1B1; Cation P1B1
*CEB FATE: Migration to ground water = Anion slow due to biodeg;
Cation slow due to biodeg

Health:

Health Summary:

Absorption is nil through the skin, based on physical/chemical properties, and good through the lung and GI tract, based on analogs. There is concern for irritation to the eye, lung, and mucous membranes, based on amines. There are also concerns for respiratory sensitization, based on [redacted], and for effects to the liver, kidney, and adrenal gland, based on submitted test data.

Test Data:

Submitted with the PMN:

Negative in Salmonella with and without activation;
Negative for chromosome aberration in V79 cells, with and without activation;
Negative in mouse lymphoma mutagenicity assay;
Rat (F) oral (gavage) LD50 > 2000 mg.kg;
Rat dermal LD50 > 2000 mg.kg;
Not a dermal irritant in rabbits;
Slight eye irritant in rabbits;
Not a dermal sensitizer in female mice;
Rat 28D oral (gavage) NOAEL 50 mg/kg, with effects to the kidney at 150 and 1000 mg/kg, and to the liver and adrenal gland at 1000 mg/kg

Ecotox:

Ecotox Values:

Fish 96-h LC50:	>100(P)	>100(M)
Daphnid 48-h LC50:	>100(P)	63.6(M)
Green algal 96-h EC50:	>100(P)	>100(M)
Fish Chronic Value:	>10(P)	
Daphnid ChV:	>10(P)	
Algal ChV:	>10(P)	

Ecotox values comments:

Predictions are based on SARs for aliphatic amines with molecular weight adjustment; SAR chemical class = aliphatic amine salt; [redacted]; solid with unknown mp (P); S = 243 g/L at 20 C (M); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; DW hardness < 150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;

Ecotoxicity Study Review for [redacted]
([redacted])

Three acute ecotoxicity studies were conducted with this PMN (P11-0049) in 2008 by [redacted] for THOR [redacted] with fish, daphnia, and algae. The PMN is a pale [redacted] at room temperature with a purity > 98%, a measured water solubility of 243 g/L, a [redacted] and an estimated vapor pressure < 0.000001 mmHg at 25°C. Concentrations were measured using an [redacted] All three tests were run under static conditions. In the fish test, measured concentrations versus nominal concentrations ranged from 94.4% to 101.4%. In the daphnia test, measured versus nominal concentrations ranged from 95% to 98%. In the algae test, measured versus nominal concentrations ranged from 97.7% to 100.4%. Because measured concentrations were close to nominals (i.e., within the 80-120 range specified by OECD) EC and LC50 values are reported as nominal concentrations. All studies complied with OCSPP and OECD guidelines for: 1) O2, pH, temperature (except for the fish test), water hardness values and other water quality parameters; 2) species, age, number of organisms per replicate, and biomass loading rates; and, 3) replicate and overall variability.

In a limit test, fasted Zebra Fish (Danio rerio) (7 fish/concentration) were exposed to nominal concentrations of 0 or 100 mg/L. The corresponding mean measured concentration in the group exposed to the test material was 97.2 mg/L. Over the course of the study, water temperature ranged from 23.1 - 25.8°C; pH ranged from 7.04 – 7.44; O2 levels ranged from 6.64 – 7.39 mg/L; water hardness was 250 mg CaCO3/L and conductivity was 14 ms/m. The 96-hour LC50 for fish was >100 mg/L (nominal) and the NOEC was 100 mg/L. The temperature exceedance in the controls (above 24°C) is not considered to compromise the test as no deaths or adverse effects occurred in the control or treated fish.

In a 48-hour immobilization test, fasted Daphnia magna (5 daphnia/replicate x 4 replicates) were exposed to nominal concentrations of 0, 10, 17.8, 31.6, 56.2, or 100.0 mg/L (corresponding to mean measured concentrations of 0, 9.66, 17.20, 31.00, 55.18, or 97.93 mg/L) under static conditions for 48 hours. Over the course of the study, water temperature ranged from 19.8 – 19.9°C; pH ranged from 7.26 – 7.68; O2 levels ranged from 6.49 – 6.83 mg/L; water hardness was 250 mg CaCO3/L and conductivity was not reported. The 48-hour EC50 for daphnia was 63.6 mg/L with 95% confidence limits of 51.2 – 76.1 mg/L. The LOEC for immobility, mortality, and abnormal signs was 31.6 mg/L and the NOEC for mortality was 17.8 mg/L.

In a 72-hour limit test for algal growth inhibition, an initial cell concentration of 1.0E+4 cells/ml of Pseudokirchneriella subcapitata was incubated with the PMN at nominal concentrations of 0 or 100 mg/L (mean measured concentration was 99.06 mg/L) under static conditions for 72 hours exposed continuously to fluorescent light with a wavelength ranging from 400 to 700 nm and an intensity ranging from 6,000 to 10,000 lux, with constant swirling (100 rpm) at 21.3 to 21.8°C. The pH ranged from 7.8 to 7.9. Cell growth was measured by fluorescence. This test met validity criteria: algal growth exceeded 16-fold over the 72-hr course of exposure in controls, the coefficient of variation of daily growth rates in controls did not exceed 35%, and the coefficient of variation of average growth in replicate control cultures did not exceed 7%. The 72-hr ErC50 for growth rate and 72-hr EbC50 for biomass both exceeded 100 mg/L, the LOEC was > 100 mg/L and the NOEC was 100 mg/L.

All three acute ecotoxicity studies are considered valid. The most sensitive species is daphnia with a 48-hour LC50 of 63.6 mg/L. A Concentration of Concern (COC) may be derived from this value by first dividing the LC50 value by a daphnia acute to chronic ratio of 10 yielding a simulated chronic value (ChV) of 6.36 mg/L. This ChV is then divided again by an assessment (uncertainty) factor of 10 to yield a COC of 0.636 mg/L, or 636 µg/L (ppb).

For comparative purposes, the ECOSAR-based COC for this PMN was > 1,000 ppb.

Ecotox Study Reviewer: S. Cragg
16 November 2010

Ecotox Factors:

Assessment Factor:	10
Concern Concentration:	636
- Chronic Value	

V. Summary of Exposures/Releases

Engineering Summary: P-11-0049

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	**Water or Air or Incineration or Landfill**	**Incineration**	**Incineration**
Descriptor A	Output 2	Output 2	Output 2
Quantity A (Release = kg/site/day; Exposure = mg/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (Release = kg/site/day; Exposure = mg/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	**Landfill**	**Water or Incineration or Landfill**	**Water or Landfill**
Descriptor A	Conservative	Output 2	Output 2
Quantity A (Release = kg/site/day; Exposure = mg/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (Release = kg/site/day; Exposure = mg/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-11-0049

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	**Water or Incineration or Landfill**	**Water or Landfill**	**Water or Air**
Descriptor A	Conservative	Output 2	Output 2
Quantity A (Release = kg/site/day; Exposure = mg/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (Release = kg/site/day; Exposure = mg/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Exposure	Exposure	Exposure
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	**Dermal**	**Inhalation**	**Dermal**
Descriptor A	High End	Upper Bound	High End
Quantity A (Release = kg/site/day; Exposure = mg/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (Release = kg/site/day; Exposure = mg/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers	[redacted]	[redacted]	[redacted]
Exposure Type	Solid	[redacted]	Solid

V. Summary of Exposures/Releases

Engineering Summary: P-11-0049

Exposures/Releases	Exposure		
Scenario	[redacted]		
Sites	[redacted]		
Media	**Inhalation**		
Descriptor A	Upper Bound		
Quantity A (Release = kg/site/day; Exposure = mg/day)	[redacted]		
Frequency A (day/year)	[redacted]		
Descriptor B			
Quantity B (Release = kg/site/day; Exposure = mg/day)			
Frequency B (day/year)			
From	[redacted]		
Workers	[redacted]		
Exposure Type	[redacted]		

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Standard Review Decision Date: 11/22/2010
Type of Decision:

Rationale: P11-0049 was placed into standard review for human health concerns and to review studies. The Standard review will consist of a T.I. and a schedule. Human health concerns were low-moderate and were for drinking water and inhalation exposures. The Agency is requesting that the submitter/company clarify the MSDS as European health standards have been referred to. Ecotoxicity concerns were moderate. Potential risks to the environment are high due to the chronic COC of 636 ppb being exceeded 122 days from [redacted] release days per year. The PMN will also be regulated under the 5(e) category for aliphatic amines for ecotoxicity concerns. The required risk-based testing will be the following; a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400),and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300). Fish and daphnid testing should be performed using the flow-through method with measured concentrations. The required risk-based testing for environmental fate will be the Ready biodegradation (OPPTS 835.3110). Test reports should include protocols approved by EPA, certificate of analysis for the test substance, raw data and results.

Summary of Exposures and Releases:
Distribution:
[redacted] sites, [redacted] d/yr, [redacted] workers
Dermal: Less than [redacted] kg/d only exposure would be from defective containers

Proc:
[redacted] sites, [redacted] d/yr [redacted] workers
Inhalation: Part: 1.5E+2 mg/day
Dermal: 3.1E+3 mg/day (Solid 100%)

Releases to water: [redacted] kg/site-day over [redacted] days/yr
or Air or Incineration or Landfill

Releases to Incineration 1: [redacted] 3 kg/yr
Releases to Incineration 2: [redacted] kg/yr

Releases to Landfill: [redacted] kg/yr

Fate Releases to water (0 % removal) Use #1 and Use #2
SWC: 128.87 ppb
DW: LADD: 7.77E-05 mg/kg/day, ADR: 6.29E-03 mg/kg/day
FI: LADD: 2.18E-09 mg/kg/day, ADR: 1.43E-04 mg/kg/day
>COC (636 ppb): 1 day

Releases to Air Fugitive Air:
LADD: 5.51E-03 mg/kg/yr ADR: 2.57E-02 mg/kg/d

Fate Releases to Landfill:
LADD: 1.54E-04 mg/kg/d

Use:
[redacted] sites, [redacted] d/yr, [redacted] workers
Inhalation: [redacted] : [redacted] mg/day
Dermal: [redacted] mg/day ([redacted]

Releases to water [redacted] kg/site-day over[redacted] days/yr
or Air
Releases to water 2: [redacted] kg/site-day over[redacted] days/yr
or Incineration or Landfill
Releases to water 3: [redacted]0 kg/site-day over [redacted] days/yr
or Incineration or Landfill
Releases to water 4: [redacted] kg/site-day over [redacted] days/yr
or Landfill
Releases to water 5: [redacted] kg/site-day over [redacted] days/yr
or Landfill

Fate Releases to water (0 % removal) Use #1 and Use #2
SWC: 6520.75 ppb
DW: LADD: 3.32E-03 mg/kg/day, ADR: 0.30 mg/kg/day
FI: LADD: 4.50E-05 mg/kg/day, ADR: 3.53E-03 mg/kg/day
>COC (636 ppb): 122 days/[redacted] days

Releases to Air Stack Air:
LADD: 2.44E-04 mg/kg/yr

Fate Releases to Landfill:
LADD: 3.44E-04 mg/kg/d

P2 Rec Comments: Halogen-free alternative to the organic halogenated flame retardants currently used in films (including medium or long-chained chlorinated paraffins, Hexabromocyclododecane, Decabromodiphenyloxide, Decabromodiphenylethane, Tris(bromoneopentyl)phosphate; usually combined with antimony trioxide as synergist). Little potential for bioaccumulation (especially when compared to organic brominated compounds).[redacted]. The focus participants agreed to not forward the claim as there was no test data to accompany the claim.

Testing:

Final Recommended:

Health:
Eco:
Fate:
Other:

SAT Report

PMN Number: **P-11-0049**
SAT Date: **11/9/2010**
Print Date: **4/20/2015**

Related cases: [redacted]
Health related cases:
Ecotox related cases: Analog: [redacted].

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	1-2	2	

Persistence	**Bioaccum**	**Toxicity**	**Comments**	
1	1	1		Anion
1	1	1		Cation

Exposure Based Review:
Health: No
Ecotox: No

Routes of exposure:
Health: Dermal Drinking Water Inhalation
Ecotox: All releases to water
Fate: ; Anion slow; Cation slow

P2Rec Comments:
Comment: No Comment

Keywords:
Keywords:
IRR-E,L,MM
UNCERT IRR-S
SENS-L
LIVER
KIDNEY
ADRENAL

Summary of Assessment:

Fate:

Fate Summary: P-11-0049

FATE: Estimations for [redacted]
log Kow = [redacted]
log Koc = [redacted]
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
FATE: Estimations for [redacted]
log Kow = [redacted]
log Koc = 1.17 (E)
log Fish BCF = 0.50 (E)
log Fish BAF = -0.05 (E)
PMN Substance: Solid
S = 243 g/L at 25 C (M)
VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = Anion 0; Cation 0
Time for complete ultimate aerobic biodeg = Anion da; Cation da-wkwk
Sorption to soils/sediments = Anion low; Cation low
PBT Potential: Anion P1B1; Cation P1B1
*CEB FATE: Migration to ground water = Anion slow due to biodeg;
Cation slow due to biodeg

Health:

Health Summary: Absorption is nil through the skin, based on physical/chemical properties, and good through the lung and GI tract, based on analogs. There is concern for irritation to the eye, lung, and mucous membranes, based on amines. There are also concerns for respiratory sensitization, based on [redacted], and for effects to the liver, kidney, and adrenal gland, based on submitted test data.

Test Data:

Submitted with the PMN:

Negative in Salmonella with and without activation;
Negative for chromosome aberration in V79 cells, with and without activation;
Negative in mouse lymphoma mutagenicity assay;
Rat (F) oral (gavage) LD50 > 2000 mg.kg;
Rat dermal LD50 > 2000 mg.kg;
Not a dermal irritant in rabbits;
Slight eye irritant in rabbits;
Not a dermal sensitizer in female mice;
Rat 28D oral (gavage) NOAEL 50 mg/kg, with effects to the kidney at 150 and 1000 mg/kg, and to the liver and adrenal gland at 1000 mg/kg

Ecotox:

Test Organism	Test	Test End	Predicted	Measured	Comments

	Type	Point			
fish	**96-h**	**LC50**	>100	>100	Limit Test
daphnid	**48-h**	**LC50**	>100	63.6	
green algal	**96-h**	**EC50**	>100	>100	Limit Test
fish	**_**	**chronic value**	>10		
daphnid	**_**	**chronic value**	>10		
algal	**_**	**chronic value**	>10		
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: Predictions are based on SARs for aliphatic amines with molecular weight adjustment; SAR chemical class = aliphatic amine salt; [redacted]; solid with unknown mp (P); S = 243 g/L at 20 C (M); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; DW hardness < 150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;

Ecotoxicity Study Review for [redacted]

Three acute ecotoxicity studies were conducted with this PMN (P11-0049) in 2008 by [redacted] for THOR GmbH Company with fish, daphnia, and algae. The PMN is a [redacted] at room temperature with [redacted] a measured water solubility of 243 g/L, [redacted], and an estimated vapor pressure < 0.000001 mmHg at 25°C. Concentrations were measured using an [redacted]. All three tests were run under static conditions. In the fish test, measured concentrations versus nominal concentrations ranged from 94.4% to 101.4%. In the daphnia test, measured versus nominal concentrations ranged from 95% to 98%. In the algae test, measured versus nominal concentrations ranged from 97.7% to 100.4%. Because measured concentrations were close to nominals (i.e., within the 80-120 range specified by OECD) EC and LC50 values are reported as nominal concentrations. All studies complied with OCSPP and OECD guidelines for: 1) O2, pH, temperature (except for the fish test), water hardness values and other water quality parameters; 2) species, age, number of organisms per replicate, and biomass loading rates; and, 3) replicate and overall variability.

In a limit test, fasted Zebra Fish (Danio rerio) (7 fish/concentration) were exposed to nominal concentrations of 0 or 100 mg/L. The corresponding mean measured concentration in the group exposed to the test material was 97.2 mg/L. Over the course of the study, water temperature ranged from 23.1 - 25.8°C; pH ranged from 7.04 – 7.44; O2 levels ranged from 6.64 – 7.39 mg/L; water hardness was 250 mg CaCO3/L and conductivity was 14 ms/m. The 96-hour LC50 for fish was >100 mg/L (nominal) and the NOEC was 100 mg/L. The temperature exceedance in the controls (above 24°C) is not considered to compromise the test as no deaths or adverse effects occurred in the control or treated fish.

In a 48-hour immobilization test, fasted Daphnia magna (5 daphnia/replicate x 4 replicates) were exposed to nominal concentrations of 0, 10, 17.8, 31.6, 56.2, or 100.0 mg/L (corresponding to mean measured concentrations of 0, 9.66, 17.20, 31.00, 55.18, or 97.93 mg/L) under static conditions for 48 hours. Over the course of the study, water temperature ranged from 19.8 – 19.9°C; pH ranged from 7.26 – 7.68; O2 levels ranged from 6.49 – 6.83 mg/L; water hardness was 250 mg CaCO3/L and conductivity was not reported. The 48-hour EC50 for daphnia was 63.6 mg/L with 95% confidence limits of 51.2 – 76.1 mg/L. The LOEC for immobility, mortality, and abnormal signs was 31.6 mg/L and the NOEC for mortality was 17.8 mg/L.

In a 72-hour limit test for algal growth inhibition, an initial cell concentration of 1.0E+4 cells/ml of Pseudokirchneriella subcapitata was incubated with the PMN at nominal concentrations of 0 or 100 mg/L (mean measured concentration was 99.06 mg/L) under static conditions for 72 hours exposed continuously to fluorescent light with a wavelength ranging from 400 to 700 nm and an intensity ranging from 6,000 to 10,000 lux, with constant swirling (100 rpm) at 21.3 to 21.8°C. The pH ranged from 7.8 to 7.9. Cell growth was measured by fluorescence. This test met validity criteria: algal growth exceeded 16-fold over the 72-hr course of exposure in controls, the coefficient of variation of daily growth rates in controls did not exceed 35%, and the coefficient of variation of average growth in replicate control cultures did not exceed 7%. The 72-hr ErC50 for growth rate and 72-hr EbC50 for biomass both exceeded 100 mg/L, the LOEC was > 100 mg/L and the NOEC was 100 mg/L.

All three acute ecotoxicity studies are considered valid. The most sensitive species is daphnia with a 48-hour LC50 of 63.6 mg/L. A Concentration of Concern (COC) may be derived from this value by first dividing the LC50 value by a daphnia acute to chronic ratio of 10 yielding a simulated chronic value (ChV) of 6.36 mg/L. This ChV is then divided again by an assessment (uncertainty) factor of 10 to yield a COC of 0.636 mg/L, or 636 µg/L (ppb).

For comparative purposes, the ECOSAR-based COC for this PMN was > 1,000 ppb.

Ecotox Study Reviewer: S. Cragg
16 November 2010

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	636	ECOSAR-based COC was >1,000 ppb
SARs	aliphatic amines with molecular weight adjustment	
SAR Class	aliphatic amine	new chemicals category: aliphatic amines
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: J. Kwiat

TEST DATA REVIEW ENGINEERING REPORT [redacted]

P-11-0049
Post-Focus Draft Revision 2 12/21/2010

ENGINEER: Choudhary \ AH
PV (kg/yr): [redacted] Import only

Revision Notes/Assessment Overview:

SUBMITTER: Thor Specialities, Inc. (submitter)

USE: Flame retardant [redacted]. Associated Cases Submitted Together: P-11-0049 and P-11-0050. P2REC: CRSS: Forward. P2 Claim: Halogen-free alternative to the organic halogenated flame retardants currently used in films (including medium or long-chained chlorinated paraffins, Hexabromocyclododecane, Decabromodiphenyloxide, Decabromodiphenylethane, Tris(bromoneopentyl)phosphate; usually combined with antimony trioxide as synergist). Little potential for bioaccumulation (especially when compared to organic brominated compounds). [redacted]

[redacted]

MSDS: Yes **LABEL**: No

Gen Eqpt: Chemical protective gloves with nitrile rubber, NBR material according to DIN EN 374 with CE-labeling; safety glasses with side shields; protective work clothing
Respirator: Put on breathing equipment (Filter P1) if dust develops
Health Effects: Non irritant on skin and eye (rabbit); not sensitizing (mouse)
TLV/PEL: - Not listed with OSHA and NIOSH.

CRSS: (11/8/2010):
Chemical Name: [redacted]
S-H2O: 243 g/L @
VP: 1.0E-6 torr @
MW: [redacted]
Physical State and Misc CRSS Info:
Neat: Solid **Mfg:** NK: Import
Proc/Form: Solid: [redacted] **End Use:** Solid: [redacted].
Submitted Data: MP = [redacted] VP < 1.2E-5 torr; WS = 243 g/L; logP [redacted]; pH = 8.5 at 100 g/L; Density = [redacted] Particle Size: [redacted] = [redacted] µm. Estimated Data: VP < 0.000001 torr (Salt).

Consumer Use: [redacted]

SAT (concerns): (11/9/2010):

Migration to groundwater: Slow
PBT rating: P1 **B**1 **T**1 Migration to groundwater = slow due to biodeg. (anion and cation)
Health: 1-2, Dermal, Drinking Water, Inhalation
Eco: 1, Water (All releases to water with a CC = 1000 ppb)

OCCUPATIONAL EXPOSURE RATING: 2-3C

NOTES & KEY ASSUMPTIONS:
Generated by the 10/25/2004 version of ChemSTEER. This is a related set; P11-0049 - 0050. Separate IRERs are prepared due to differences in SAT. However, note the PMNs have [redacted], [redacted], and [redacted]. // The submitter has been contacted for additional information, see contact report. The PMN is imported; therefore, manufacturing is not assessed. This IRER assesses releases and exposures to PMN during [redacted] per submitter information. Because no information is provided for end use, this IRER references the 2004 draft interim Generic Scenario on [redacted]. Releases to air, water, incineration and landfill are expected. Dermal exposure to solid and inhalation exposure to [redacted] are also assessed. // No [redacted] case was found. Other similar past cases referenced for consistency are: [redacted] (flame retardants [redacted] All past cases were import only (consistent with this IRER). [redacted] assessed [redacted] g and assumed the PMN is entrained [redacted] This IRER conservatively presents release and exposure estimates from both [redacted] All past cases assessed inhalation exposure to [redacted] (consistent with this IRER). Dermal exposure assessment was not required in past cases (this IRER assesses dermal exposure to solids).

POLLUTION PREVENTION CONSIDERATIONS:
P2 Claim: - Highly efficient FR that allow lower dosage and thus preserve better material properties of the treated polymer (e.g., films with better impact resistance and elongation values, transparency of treated films can be retained). - Halogen-free alternative to the organic halogenated FR currently used in films (include medium or long-chained chlorinated paraffins, Hexabromocyclododecane, Decabromodiphenyloxide, Decabromodiphenylethane, Tris(bromoneopentyl)phosphate; usually combined with antimony trioxide as synergist). - Little potential for bioaccumulation (especially when compared to organic brominated compounds). - Less release of corrosive gases in the event of a fire. - Generally lower smoke toxicity (CO) in the event of a fire. - Lower smoke density in the event of a fire. P2REC: CRSS: Forward.

P2 REC:

EXPOSURE-BASED REVIEW: No **(0 criteria met)**

P-11-0049

Use:

Number of Sites/Location: submitter site(s)

Basis: The submission contains no information on). / kg resin) / sites) / /yr) = kg/site-day. According to the GS estimate, there would only be use site. Because there are CEB assumes that there would be at least use sites. Additionally, CEB assumes day/yr operation as default (consistent with GS).

Process Description:

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water or Incineration or Landfill
Output 2: kg/site-day over day/yr from sites or kg/yr
to: Water, incineration or landfill (GS)
from:
basis

Water or Landfill
Output 2: kg/site-day over day/yr from sites or kg/yr
to: Water or landfill (GS)
from:
basis: .

Water or Air
Output 2: kg/site-day over day/yr from sites or kg/yr
to: Water or air (GS)
from:
basis: .

Water or Landfill
Output 2: kg/site-day over day/yr from sites or kg/yr
to: Water or landfill (GS)
from:
basis:

Water or Incineration or Landfill
Conservative: kg/site-day over day/yr from sites or kg/yr

to: Water, incineration or landfill (GS)
from: [redacted]
basis: [redacted]

RELEASE TOTAL

[redacted] kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: [redacted]
Basis: The [redacted] GS estimates [redacted] workers/site.

Inhalation:

Exposure to [redacted]
Upper Bound: [redacted] 1 mg/day over [redacted] days/yr
Number of workers (all sites) with Inhalation exposure: [redacted]
Basis: [redacted]

INHALATION MONITORING DATA REVIEW

1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): Yes
2) (a) Exposure level > 1 mg/day? Yes
(b) Hazard Rating for health of 2 or greater? No
Inhalation Monitoring Data Desired? Yes (both criteria met)

Dermal:

Exposure to Solid
High End: 4.7E+2 mg/day over [redacted] days/yr
Number of workers (all sites) with Dermal exposure: [redacted]
Basis: [redacted]

P-11-0049

Distribution

Number of Sites/Location: [redacted] submitter site(s)
[redacted]
Basis:
Process Description: [redacted]

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

[redacted]

RELEASE TOTAL

[redacted] kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes:
Basis:

P-11-0049

Processing: [redacted]

Number of Sites/Location: [redacted] submitter site(s)
unknown site(s)
Basis: Submission estimates [redacted] sites and [redacted] days/yr.
Process Description: [redacted]

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Landfill
Conservative: [redacted] 2 kg/site-day over [redacted] day/yr from [redacted] sites or [redacted] kg/yr
to: [redacted] (submission)
from: [redacted]
basis: [redacted]

Incineration
Output 2: [redacted] kg/site-day over [redacted] day/yr from [redacted] sites or [redacted] kg/yr
to: [redacted]
from: [redacted]
basis: [redacted] Submission estimates [redacted]

Water or Air or Incineration or Landfill
Output 2: [redacted] kg/site-day over [redacted] day/yr from [redacted] sites or [redacted] kg/yr
to: Air, water, incineration or land ([redacted] Model)
from: [redacted]
basis: [redacted]

Incineration
Output 2: [redacted] kg/site-day over [redacted] day/yr from [redacted] sites or [redacted] kg/yr
to: [redacted]
from: [redacted]

RELEASE TOTAL

[redacted] kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: [redacted]
Basis: Submission estimates a [redacted]/site. CEB assumes all workers are exposed to the pure PMN substance as conservative. Since the PMN [redacted] exposure to [redacted] is expected to be mitigated through PPE and controls.

Inhalation:

Exposure to [redacted]
Upper Bound: [redacted] mg/day over [redacted] days/yr
Number of workers (all sites) with Inhalation exposure: [redacted]
Basis: [redacted]

INHALATION MONITORING DATA REVIEW

1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): Yes
2) (a) Exposure level > 1 mg/day? Yes
(b) Hazard Rating for health of 2 or greater? No
Inhalation Monitoring Data Desired? Yes (both criteria met)

Dermal:

Exposure to Solid
High End: 3.1E+3 mg/day over [redacted] days/yr
Number of workers (all sites) with Dermal exposure: [redacted]
Basis: [redacted]